General

Guideline Title

Progestogen-only implants

Bibliographic Source(s)

Clinical Effectiveness Unit. Progestogen-only implants. London (UK): Faculty of Sexual and Reproductive Healthcare; 2014 Feb. 25 p. [92 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Clinical Effectiveness Unit. Progestogen-only implants. London (UK): Faculty of Sexual and Reproductive Healthcare; 2008 Apr. 16 p.

Recommendations

Major Recommendations

The recommendation grades (A to C, Good Practice Point) are defined at the end of the "Major Recommendations" field.

Who Is Eligible to Use Progestogen-only Implants?

Health professionals should be familiar with the most up to date UK Medical Eligibility Criteria for the progestogen-only implant. (Good Practice Point)

Timing of Repeat Insertions

If an implant is replaced immediately, and after no longer than 3 years since insertion, there is no need for additional contraceptive precautions after replacement. (Grade C)

What Are the Benefits and Risks of Progestogen-only Implant Use?

Non-contraceptive Benefits

The progestogen-only implant may help to alleviate dysmenorrhoea. (Grade C)

Health Concerns

Cardiovascular Health

There is little or no increased risk of venous thromboembolism, stroke or myocardial infarction associated with the use of the progestogen-only implant. (Grade C)

Bone Mineral Density

There is no evidence of a clinically significant adverse effect on bone mineral density with use of a progestogen-only implant. (Grade B)

Side Effects

Changes to Bleeding Patterns

Fewer than one-quarter of women using the progestogen-only implant will have regular bleeds. Infrequent bleeding is the most common pattern (approximately one-third); around one-fifth of women experience no bleeding; and approximately one-quarter have prolonged or frequent bleeding. Altered bleeding patterns are likely to remain irregular. (Grade C)

Changes in Weight, Mood, Libido

Although some women do report changes in weight, mood and libido when using the progestogen-only implant, there is no evidence of a causal association. (Grade C)

Acne

Women may experience improvement, worsening or new onset of acne during use of a progestogen-only implant. (Grade C)

Headache

Although some women report headache with use of the progestogen-only implant, there is no evidence of a causal association. (Grade C)

How Should the Progestogen-only Implant Be Inserted, Removed and Replaced?

Training Requirements

Health professionals who insert and/or remove progestogen-only implants should be appropriately trained, maintain competence and attend regular updates. (Grade C)

Anaesthesia

Appropriate local anaesthesia should be administered prior to insertion and removal of a progestogen-only implant. (Good Practice Point)

Removal

There is no need for additional precautions or abstinence prior to removal of a progestogen-only implant, providing the removal occurs no later than 3 years after insertion. (Grade C)

After removal of a progestogen-only implant, effective contraception is required immediately if pregnancy is not desired. (Grade B)

What Information Should Be Given to Implant Users about Continuation and Follow-up?

Women using progestogen-only implants should be advised that no routine follow-up is required, but that they can return at any time to discuss problems or change their contraceptive method. (Good Practice Point)

Women using a progestogen-only implant should be advised to return if: they cannot feel their implant or if it appears to have changed shape; they notice any skin changes or pain around the site of the implant; they become pregnant; or they develop any condition that may contraindicate continuation of the method. (Good Practice Point)

What Factors Might Reduce the Efficacy of the Progestogen-only Implant?

Drug Interactions

Concomitant use of enzyme-inducing drugs may reduce the efficacy of the progestogen-only implant. Women should be advised to switch to a method unaffected by enzyme-inducing drugs or to use additional contraception until 28 days after stopping the treatment. (Grade C)

Weight

Obesity (body mass index [BMI] >30kg/m^2) is a condition for which there is no restriction on the use of the progestogen-only implant (UK Medical Eligibility Criteria for Contraceptive Use 1). (Grade C)

No increased risk of pregnancy has been demonstrated in women weighing up to 149 kg. However, because of the inverse relationship between weight and serum etonogestrel levels, a reduction in the duration of contraceptive efficacy cannot be completely excluded. (Grade C)

Women using the progestogen-only implant should be informed, where relevant, that the manufacturer states that earlier replacement can be considered in 'heavier' women but that there is no direct evidence to support earlier replacement. (Good Practice Point)

What Other Issues Should Women Be Advised to Consider?

Sexually Transmitted Infections and Testing

The consistent and correct use of condoms is the most efficient means of protecting against human immunodeficiency virus (HIV) and other sexually transmitted infections. (Grade B)

Managing Problems Associated with Progestogen-only Implant Use

Impalpable Implant

A woman with an impalpable implant should be advised to use additional precautions or avoid intercourse until the presence of an implant is confirmed. (Good Practice Point)

The location of an impalpable or deep implant should be identified before exploratory surgery. Referral to an expert implant removal centre is recommended. The location of an impalpable or deep implant should be identified before exploratory surgery. Referral to an expert implant removal centre is recommended. (Good Practice Point)

Problematic Bleeding

After exclusion of other causes, women who experience troublesome bleeding while using the progestogen-only implant, and who are eligible to use combined hormonal contraception, may be offered combined oral contraception (COC) cyclically or continuously for 3 months (outside product licence). Longer-term use of the implant and COC has not been studied and is a matter of clinical judgement. (Good Practice Point)

Pregnancy

The progestogen-only implant is not known to be harmful in pregnancy but women with a continuing pregnancy should be advised to have the implant removed. Women may retain the implant if they wish to continue the method after a non-continuing pregnancy. (Grade C)

Definitions:

Grades of Recommendations

A: Evidence based on randomised controlled trials

B: Evidence based on other robust experimental or observational studies

C: Evidence is limited but the advice relies on expert opinion and has the endorsement of respected authorities

Good Practice Point: Where no evidence exists but where best practice is based on the clinical experience of the guideline group

Clinical Algorithm(s)

An algorithm titled "Management of Impalpable Implant" is provided in the original guideline document.

Scope

Disease/Condition(s)

Unintended pregnancy

Guideline Category

Counseling

Evaluation

Management

Prevention

Risk Assessment

Clinical Specialty

Family Practice

Internal Medicine

Obstetrics and Gynecology

Preventive Medicine

Intended Users

Advanced Practice Nurses

Nurses

Patients

Physician Assistants

Physicians

Public Health Departments

Guideline Objective(s)

To provide evidence-based recommendations and good practice points on use of the progestogen-only implant

Target Population

Women using or considering use of progestogen-only implants as a long-term option to prevent pregnancy

Interventions and Practices Considered

1. Assessment of medical eligibility criteria for use of progestogen-only implants
2. Timing of implant insertion (first and repeat insertions)
3. Consideration of benefits and risks of progesterone-only implant use (non-contraceptive benefits, health concerns, side effects)
4. Inserting, removing, and replacing progestogen-only implants
5. Providing advice to women about continuation and follow-up
6. Providing advice to women about drug interactions that may reduce efficacy of the progestogen-only implant
7. Providing advice to "heavier" women about earlier replacement of implants
8. Providing advice on sexually transmitted infections and testing, consistent use of condoms, and emergency contraception
9. Managing problems associated with progestogen-only implants

Major Outcomes Considered

- Contraceptive efficacy
- Unintended pregnancy rate
- Non-contraceptive benefits (dysmenorrhea, ovulatory pain)
- Side effects of progestogen-only implant use
- Health concerns (i.e., breast cancer, cardiovascular, ectopic pregnancy, gynaecological concerns, bone mineral density, acne, headache)
- Cost-effectiveness

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Evidence is identified using a systematic literature review and electronic searches are performed for: MEDLINE (CD Ovid version) (1996–2013); EMBASE (1996–2013); PubMed (1996–2013); The Cochrane Library (to 2013) and the US National Guideline Clearinghouse. The searches are performed using relevant medical subject headings (MeSH), terms and text words. The Cochrane Library is searched for relevant systematic reviews, meta-analyses and controlled trials relevant to progestogen-only implants. Previously existing guidelines from the Faculty of Sexual Reproduction & Healthcare (formerly the Faculty of Family Planning and Reproductive Health Care), the Royal College of Obstetricians and Gynaecologists (RCOG), the World Health Organization (WHO) and the British Association for Sexual Health and HIV (BASHH), and reference lists of identified publications are also searched. Similar search strategies have been used in the development of other national guidelines.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Not Given)

Rating Scheme for the Strength of the Evidence

Not stated

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Selected key publications are appraised using standard methodological checklists similar to those used by the National Institute for Health and

Care Excellence (NICE). All papers are graded according to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system. Recommendations are graded using a scheme similar to that adopted by the Royal College of Obstetricians and Gynaecologists (RCOG) and other guideline development organisations (see the "Rating Scheme for the Strength of the Recommendations" field). The clinical recommendations within this Guidance are based on evidence whenever possible. Summary evidence tables are available on request from the Clinical Effectiveness Unit (CEU). The process for the development of CEU guidance is detailed on the Faculty of Sexual and Reproductive Healthcare website (see the "Availability of Companion Documents" field). The methods used in the development of this guidance have been accredited by National Health Service (NHS) Evidence.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Clinical Effectiveness Unit (CEU) Guidance is developed in collaboration with the Clinical Effectiveness Committee (CEC) of the Faculty of Sexual & Reproductive Healthcare (FSRH). The CEU Guidance development process employs standard methodology and makes use of systematic literature review and a multidisciplinary group of professionals. The multidisciplinary group is identified by the CEU for their expertise in the topic area and typically includes clinicians working in family planning, sexual and reproductive health care, general practice, other allied specialties, and user representation. In addition, the aim is to include a representative from the FSRH CEC, the FSRH Meetings Committee and FSRH Council in the multidisciplinary group.

Recommendations are based primarily on evidence directly relating to both forms of the etonogestrel implant (referred to as the progestogen-only implant) and consensus opinion of experts. Where there is limited evidence, extrapolation of data from other progestogen-only implants (Norplant® and Jadelle®) has been used. As Nexplanon and Implanon are bioequivalent, recommendations other than those relating to insertion and localisation apply equally to both products.

Drafting the Document

Guidelines are initially drafted by the CEU Researcher and Director. The CEU researcher has responsibility for undertaking the literature search, appraising documents, preparing evidence tables and writing the initial draft of the document. This is then sent to the CEU Director who reviews and amends the document accordingly. Drafts are subsequently reviewed by a selected Multidisciplinary Group (MDG), the FSRH CEC, and independent peer reviewers before a draft is prepared for public consultation. It is the responsibility of the CEU researcher and Director to review any feedback submitted by the MDG, CEC, independent peer reviewers and wider public and amend the document accordingly.

Formulating Recommendations

Each recommendation is formulated so that it is specific for a defined patient group in defined situations. The patient group(s) and situation(s) are consistent with the specified scope of the guidance. Search strategies are implemented looking at the population in question, the intervention, e.g., contraceptive and outcome of interest, e.g., safety, bone health, weight gain. Where relevant the corresponding UK Medical Eligibility Criteria (UKMEC) category is stated.

Following critical appraisal of the available evidence, recommendations are initially drafted by the CEU. Each recommendation is graded and the grading presented clearly next to the recommendation.

Consensus

- The first draft of the document is circulated to members of the MDG for comment. Members may provide feedback on the body of text and also the recommendations.
- Recommendations may be redrafted in light of feedback from the MDG.
- The CEU will continue to receive feedback on the text and recommendations with future drafts.
- From May 2011 at the penultimate draft stage prior to issuing guidance for public consultation individuals of the MDG will be asked to score recommendations using Likert scale 1-3 agree 7-9 disagree.
- Consensus will be reached when 80% of those responding score 1-3.
- Recommendations where consensus is not reached will be redrafted in light of any feedback.
- The consensus scoring sheets will be sent again for all recommendations. Consensus will be reached when 80% of those responding score 1-3.

- If consensus is not reached on certain recommendations, these will be redrafted once more. If after one more round of scoring consensus is still not reached, the recommendation will be taken to the CEC for final decision. Any group member who is not content with the decision can choose to have their disagreement noted within the guidance.

Rating Scheme for the Strength of the Recommendations

Grading of Recommendations

A: Evidence based on randomised controlled trials

B: Evidence based on other robust experimental or observational studies

C: Evidence is limited but the advice relies on expert opinion and has the endorsement of respected authorities

Good Practice Point: Where no evidence exists but where best practice is based on the clinical experience of the guideline group

Cost Analysis

It has been advised that increasing the uptake of long-acting reversible contraception (LARC) such as the progestogen-only implant will reduce unintended pregnancies. Use of the progestogen-only implant is cost-effective at 1 year of use. The implant is more cost-effective than combined oral contraception or progestogen-only injectables. The intrauterine device is more cost-effective than the implant, but the incremental cost-effectiveness ratio decreases over time. The implant is more cost-effective than the levonorgestrel-releasing intrauterine system (LNG-IUS) with 3 years of use, after which the LNG-IUS becomes more cost-effective.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Drafts are reviewed by a selected Multidisciplinary Group (MDG), the Faculty of Sexual and Reproductive Healthcare (FSRH) Clinical Effectiveness Committee (CEC), and independent peer reviewers before a draft is prepared for public consultation. It is the responsibility of the CEU researcher and Director to review any feedback submitted by the MDG, CEC, independent peer reviewers and wider public and amend the document accordingly.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- The implant is a highly effective contraceptive. The overall pregnancy rate reported in the National Institute of Health and Care Excellence (NICE) guideline on *Long-acting Reversible Contraception* is <1 in 1000 over 3 years. A review of contraceptive failure in the USA has estimated that the percentage of women in the USA experiencing an unintended pregnancy within the first year of using the progestogen-only

implant is 0.05%.
- Dysmenorrhoea and ovulatory pain that are not associated with any identifiable pathological condition may be alleviated by hormonal methods that inhibit ovulation, and improvements have been noted with the progestogen-only implant.

Potential Harms

- Unscheduled bleeding in the first 3 months after starting a new hormonal contraceptive method is common. The progestogen-only implant is associated with unpredictable bleeding patterns; however, the bleeding pattern in the first 3 months is broadly predictive of future bleeding patterns for many women. Dissatisfaction with bleeding has been cited as a reason for implant discontinuation. Infrequent bleeding (<2 episodes of bleeding/spotting over a 90-day period according to the World Health Organization definition) is common, with around one-third of implant users in clinical trials experiencing this scenario. Amenorrhoea (no bleeding over a 90-day period) has been cited in around 21% of users; prolonged bleeding (≥1 bleeding/spotting episode occurring on ≥10 days in a 90-day period) in around 17% of users; and around 6% of users have reported frequent bleeding (>4 episodes of bleeding/spotting in a 90-day period).
- There are reports of women experiencing weight gain and mood changes whilst using the progestogen-only implant. Decreased libido is listed within the summary of product characteristics (SPC) as a commonly (between 1 in 100 to 1 in 10) reported undesirable effect within clinical trials. Non-comparative studies have reported decreased libido in fewer than 6% of users of progestogen-only implants.
- Progestogen-only implant use may affect acne in some women. Acne has been shown to occur, improve or worsen with the use of a progestogen-only implant.
- Headache is very commonly reported in clinical trials of the progestogen-only implant and the SPC includes headache as a possibly related undesirable effect. However, headaches are a common symptom in the general population and the National Institute for Health and Care Excellence (NICE) indicates that a causal relationship cannot be confirmed.
- Skin atrophy is recognised as a potential adverse effect of steroid hormone use, and there are case reports in the literature of atrophy at the site of subdermal implants.
- Non-insertion of the implant, deep insertion and nerve injury are three types of harm cited in litigation cases involving the contraceptive implant. Vascular injury and rarely intravascular insertion have also been reported. Estimating the frequency with which such events happen is difficult as much of the evidence comes from postmarketing surveillance and case reports.
- Deep implant insertions are more likely a result of the insertion technique. If an implant is inserted too deeply it may be difficult to remove and/or locate, and there is greater potential for neurovascular injury, infection and scar formation.
- Incidents of nerve injury and neuropathy associated with the insertion or removal of Implanon are documented in the literature.
- Fibrosis around the implant and implant breakages have been documented as possible complications. Through the Faculty of Sexual and Reproductive Healthcare enquiry service anecdotal reports have been received of implants being sited too superficially, causing pain and altered sensation.
- An impalpable implant should not be assumed to be a deep implant. Any woman with an impalpable implant should be advised to use additional precautions or avoid intercourse until further investigation can be undertaken and the presence of an implant confirmed. The need for emergency contraception and a pregnancy test should be considered if there has been a potential risk.
- As with all procedures there is a risk of collapse due to a vasovagal reaction or anaphylaxis.

Qualifying Statements

Qualifying Statements

Qualifying Statements

The recommendations should be used to guide clinical practice but they are not intended to serve alone as a standard of medical care or to replace clinical judgement in the management of individual cases.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Audit Criteria/Indicators

Clinical Algorithm

Staff Training/Competency Material

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Clinical Effectiveness Unit. Progestogen-only implants. London (UK): Faculty of Sexual and Reproductive Healthcare; 2014 Feb. 25 p. [92 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2008 Apr (revised 2014 Feb)

Guideline Developer(s)

Faculty of Sexual and Reproductive Healthcare - Professional Association

Source(s) of Funding

Faculty of Sexual and Reproductive Healthcare

Guideline Committee

Composition of Group That Authored the Guideline

Guideline Development Group: Dr Louise Melvin, Director, Clinical Effectiveness Unit; Ms Julie Craik, Researcher, Clinical Effectiveness Unit; Dr Fiona Boyd, FSRH Meetings Committee Representative, Associate Specialist, Highland Sexual Health, Raigmore Hospital, Inverness; Dr Rachel D'Souza, Consultant in Sexual and Reproductive Health, Margaret Pyke Centre, London; Dr Val Godfree, Integrated Clinical Lead for Sexual Health, Western Sussex Hospitals NHS Trust, West Sussex; Ms Lynn Hearton, FSRH Clinical Effectiveness Committee and user representative, Helpline and Information Services Manager, Family Planning Association, London; Dr Asha Kasliwal, FSRH Clinical Standards Committee representative, Consultant in Sexual and Reproductive Health, Central Manchester University Hospital, Manchester; Dr Susan MacPherson, Specialty Doctor, Tayside Sexual and Reproductive Health Services Drumhar Health Centre, Perth; Dr Sam Rowlands, Clinical Lead in Contraception and Sexual Health, Dorset Healthcare University NHS Foundation Trust, Bournemouth; Dr Raj Sharma, Specialty Doctor, Palatine Contraception and Sexual Health, The Hathersage Centre, Manchester; Ms Cath Shelley, Clinical Nurse Specialist–Sexual Health, Sexual Health Services, Community Health Services Division, Blackpool Teaching Hospitals NHS Foundation Trust, Blackpool; Dr Martyn Walling, General Practitioner, Westside Surgery, Sleaford Road Medical Centre, Boston, Lincolnshire; Dr Samantha Whiteside, General Practitioner, Kincorth Medical Centre and Cove Bay Medical Practice, Aberdeen

Financial Disclosures/Conflicts of Interest

No relevant interests were declared.

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Clinical Effectiveness Unit. Progestogen-only implants. London (UK): Faculty of Sexual and Reproductive Healthcare; 2008 Apr. 16 p.

Guideline Availability

Electronic copies: Available in Portable Document Format (PDF) from the Faculty of Sexual and Reproductive Health Care Web site .

Print copies: Available from the Faculty of Sexual and Reproductive Health Care, 27 Sussex Place, Regent's Park, London NW1 4RG

Availability of Companion Documents

The following is available:

- Faculty of Sexual and Reproductive Healthcare: Clinical Effectiveness Unit. Framework for guideline development. London (UK): Faculty of Sexual and Reproductive Healthcare; 2011 May. 35 p. Electronic copies: Available in Portable Document Format (PDF) from the Faculty of Sexual and Reproductive Healthcare Web site .

In addition, questions for continuing professional development, auditable outcomes, and equipment recommended for insertion or removal of a progestogen-only implant are available in the original guideline document .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI on July 9, 2008. This summary was updated by ECRI Institute on June 2, 2014.

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